REMARKS

Upon entry of this amendment, claims 1-39 and 47-51 are pending. Claims 36 and 44-46 are canceled without prejudice or disclaimer, with claims 44-46 being duplicative of claims 31-33. Applicants reserve the right to file a divisional application on any canceled subject matter.

Claims 1, 34 and 37 have been amended and claims 47-51 have been added. The amended claims are supported by the original claims and/or the specification as filed. Specific support for the language "solution does not comprise one or more flavoring oils" in claim 1 is found on page 8, lines 3 - 6. The amendments to the claims have been made to more clearly define the present invention and are not meant to limit the scope of the claims to the specific examples.

Claim Objections

Claims 44 and 45 are objected to as being substantially duplicate to pending claims 31-33. It is believed that the Examiner intended to reject claims 44-46 on this basis. Applicants have canceled claims 44-46 which were inadvertently added in the previous response and the cancellation of these claims is not intended to surrender the subject matter encompassed by these claims as claims 31-33 are still pending in this application.

Rejections under 35 U.S.C.§ 102(b)

Hall (U.S. 5,405,604)

Claims 1-8, 10-13 and 25-27 are rejected as allegedly being anticipated by Hall (U.S. 5,405,604) ("Hall"). The Examiner has rejected claims 1-8, 10-13, 25-27, 31 and 34-38 in the first line of this rejection under item 3 on page 2 but the last sentence of item 3 on page 3, recites that this rejection is maintained as to claims 1-8, 10-13 and 25-27. Applicants' attorney contacted the new examiner, Examiner Seidleck, who clarified this discrepancy by stating the only claims 1-8, 10-13 and 25-27 were rejected as anticipated by Hall.

The Examiner alleges that Hall discloses a concentrated mouthrinse comprising about 0.05% to about 10% cationic antimicrobial agent, about 30 to about 85% of propylene glycol, polyethylene glycol, and mixtures thereof; and water as recited in claim 1. The Examiner states that although Applicants have amended claim 1 to delete the term

"about" so that the claim now recites greater than 10% by weight, the Examiner alleges that Hall still reads on Applicants' claim because Hall recites the term "about" in his claim. The Examiner acknowledges that Applicants' arguments regarding the flavoring oil made in the previous response were persuasive.

In an effort to more clearly define the present invention from the mouthwash of Hall, Applicants have amended claim 1 to recite that the "...solution does not comprise one or more flavoring oils." As noted above in the remarks, this language is supported in the specification on page 8, lines 3-6.

As all of the rejected claims depend from amended claim 1, it is requested that this rejection be withdrawn.

Ryan (U.S. 4,472,373)

Claims 1-13, 21, 25-27, 31, 34-39 and 44 are rejected as allegedly being anticipated by Ryan (U.S. 4,472,373) ("Ryan"). The Examiner alleges that Ryan discloses oral compositions, such as toothpastes, mouthwashes, lozenges and chewing gum containing an antimicrobial agent which is effective against plaque/gingivitis and mouth odor. In particular, the Examiner states that Ryan discloses antimicrobials that include an N-tetradecylpyridinium salt and/or a N-tetradecyl-4-ethyl-pyridinium salt and further discloses that the concentration of these antimicrobials in his formulation can range from 0.001% to about 20%. Further, the Examiner states that Ryan discloses that mouthwash formulations generally comprise about 20:1 to about 2:1 of a water/ethyl alcohol solution.

Applicants respectfully disagree with the Examiner's characterization of Ryan. Although Ryan discloses the range of the antimicrobial concentration of 0.001 – 20%, it does not disclose a solution that contains an antimicrobial agent with a concentration of greater than 0.5%. For example, in col. 4, lines 11-31, a mouthwash composition is disclosed, and lines 28-30 specifically recite that the typical amount of an antimicrobial agent in mouthwashes is from about 0.01 to about 0.5% by weight. Further, Example I discloses two flavored alcoholic solutions given to Group A and Group B subjects in which the pyridinium salt was 0.075% (col. 5, lines 32-37). Additionally, Example II shows a mouthwash containing a pyridinium salt (TDEPC) at a concentration of 0.075% in a flavored ethanol/glycerin solution. The last example, Example III, discloses pyridinium test solutions at a concentration of 0.1% in water. It is also noted that the highest

concentration of antimicrobial agent; i.e., from about 0.05% to 7%, is found in dentifrices (see col. 3, lines 1-2), which are not solutions as required by the present claims but rather are pastes. The disclosed dentifrices and their components are disclosed in col. 3, line 1 to col. 4, line 10.

Ryan fails to disclose a solution that contains each of the components of claim 1. Ryan fails to disclose any specific examples of a solution containing a pyridinium salt with a concentration falling within the claimed range of the quaternary ammonium compound of the present invention. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." See MPEP 2131.03, second heading, on page 2100-72.

An invention lacks novelty under 35 U.S.C. §102 if each and every element of the claim is described or disclosed, either explicitly or inherently, in a single prior art reference. *Finnigan Corp. v. International Trade Com'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). Such a reference is said to "anticipate" the invention, which renders the implicated claim invalid. Anticipation is a question of fact, which can be decided by a jury. *Finnigan*, 180 F.3d at 1362. Further, [T]he identical invention must be shown in as complete detail as is contained in the ... claims." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed.Cir. 1989).

Applicants assert that Ryan fails to show a single solution that discloses each and every element as set forth in the claim. Nor does Ryan disclose the claimed invention in complete detail. None of Ryan's examples of solutions containing antimicrobial agents come remotely close to a concentration of greater than 10%, and in fact, the solutions disclosed in Ryan utilize much lower concentrations; i.e., 0.075%, 0.1 % or up to 0.5%.

Applicants also point out that the solutions disclosed in the examples all contain a flavoring agent, except for Example III, in which the pyridinium salt is prepared in water. In view of all of these arguments, it is requested that this rejection be withdrawn as not anticipating the rejection claims.

Rejections under 35 U.S.C. §103

Hall (U.S. 5,405,604) in view of Dickson (U.S. 5,520,575)

Claims 1-39 are rejected as obvious over Hall in view of Dickson (U.S. 5,520,575) ("Dickson"). The Examiner alleges that Hall discloses a maximum concentration of cationic antimicrobial agent of about 10%, and that Hall does not disclose a concentration of cationic antimicrobial agent of about 15%, about 20%, and about 40%. The Examiner further alleges that Dickson, in column 4, lines 12-35, discloses that the concentration of antimicrobial agents typically range from about 1 to about 30%. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention was made to vary the concentration of the antimicrobial agent and delivery mechanism based on its intended purpose with the expected result being a successful product.

The Examiner further states that the arguments presented in the previous response with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection. This comment is not understood. This obviousness rejection based on Hall in view of Dickson is the same rejection that was made for the same reasons by the Examiner in the previous rejection. Therefore, it is unclear why the previous arguments are considered moot because there are no new grounds of rejection. Clarification is requested.

Applicants respectfully disagree with the examiner's interpretation of Dickson. As explained in the previous response, Dickson discloses a method for reducing contamination of animal carcasses during slaughtering comprising applying a wetting solution to the carcass concurrently with hide removal. Moreover, Dickson states that the wetting solution reduces the stickiness of the exposed carcass surface so fewer contaminants adhere to the surface, or adhere less tightly, thus improving subsequent cleaning efficiency. From a reading of Dickson, the important property of the wetting solution is the reduction of the stickiness of the surface of the carcass by reducing surface tension that results from a residual film of water on the surface of the carcass following treatment. Dickson surmises that this film of water likely hydrates the surface proteins which begin to uncoil, destroying the characteristic shape of the protein and along with it the characteristic adhesive property. Further, Dickson states that the water layer interferes with the binding of contaminants to the carcass surface.

Although the wetting solution of Dickson may contain an aqueous antimicrobial solution, the presence of this agent is not necessary in a method of reducing contamination as disclosed in Dickson. In fact, water alone works well to reduce contamination and is sufficient for the efficacy of the claimed method.

In column 4, lines 29-35 of Dickson, as referenced by the Examiner, it is recited that the concentration of the antimicrobial agent depends on the particular antimicrobial agent or combination of agents used or the degree of contamination. Dickson then recites ranges of concentrations of antimicrobial agents useful in the claimed method.

Applicants respectfully disagree with the Examiner rationale for combining Hall and Dickson to allegedly render the claimed composition obvious. The Examiner's rejection appears to be suggesting that it would be obvious to modify the mouthrinse of Hall as suggested by Dickson, which according to the Examiner, suggests that it would be obvious to vary the concentration of the antimicrobial agent and delivery mechanism based upon the intended purpose of the antimicrobial agent. But the Dickson wetting solution does not require the presence of an antimicrobial agent for the solution to function to reduce contamination. Again to emphasize Applicants' position, "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 31 USPQ2d 1130 (Fed. Cir. 1994). Thus, a person skilled in the art would not necessarily be motivated to combine the teachings of Hall and Dickson to arrive at the composition of the present invention. In fact, if a skilled person read that Dickson's wetting solution does not require an antimicrobial agent, and yet still reduces microbial contamination, there is no motivation to combine Hall and Dickson.

Applicants respectfully point out that the Examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining elements to make out a *prima facie* case of obviousness, the Examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make the combination and (ii) a reasonable expectation that the combination would succeed. Both the suggestion and reasonable expectation must be found within the prior art, and not be gleaned from Applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). The Examiner has failed

to support the alleged case of *prima facie* obviousness, and as a result of these deficiencies, it is requested that this rejection be withdrawn.

Applicants further wish to point out that a solution containing a concentration of QAC of greater than 10%, and in some claims the QAC concentration is as high as about 60% by weight, in combination with at least one solubility enhancing agent, and that does not contain one or more flavoring oils. As has been discussed previously, Hall contains a flavoring oil as an essential component of his solution. Applicants set forth the many advantages of the claimed concentrated QAC solution on page 6 of the previous response filed on April 30, 2001, and the Examiner is referred to this discussion as well as the many advantages of the claimed concentrated composition in the paragraph bridging pages 12 and 13 of the specification, and take these advantages of the claimed solution into consideration with the above arguments, and withdraw the rejection.

This combination of Hall and Dickson does not apply to claim 39 for all of the reasons argued above. As a result of all of the arguments provided above, it is requested that the Examiner withdraw the rejection of claims 1-39.

Hall (U.S. 5,405,604) in view of Bevilacqua (U.S. 5,693,315)

Claims 1-13, 21, 25-27, 31, and 33-39 are rejected as obvious over Hall in view of Bevilacqua ("Bevilacqua"). The Examiner applies Hall as discussed above. Bevilacqua allegedly discloses a mammal tooth treating composition that typically contains an antimicrobial compound in the range from 0.75 to 20%. The Examiner states that it would have been obvious to one of ordinary skill in the art to vary the concentration of the antimicrobial compound based on the teachings of Bevilacqua that the concentrations can range from 0.75 to 20 %, with the expectation of a successful product.

Again, Hall contains flavoring oils as an essential component. The claimed solution does not. Bevilacqua does not disclose a solution that contains an antimicrobial compound but rather discloses a paste or a gel that may be burnished into the surface of the tooth (col. 2, lines 46-50). There is no motivation from either of these patent disclosures to modify the solution of Hall by increasing the concentration of the antimicrobial compound based on the disclosure in the Bevilacqua paste. This combination of Hall and Bevilacqua does not apply to claim 39 for all of the reasons argued above, and it is requested that this rejection be withdrawn to all of the rejected claims.

Ryan (U.S. 4,472,373) in view of Hall (U.S. 5,405,604)

Claims 1-39 and 44-46 are rejected as allegedly being obvious over Ryan in view of Hall. The Examiner alleges that Ryan discloses that additional ingredients may be included in his mouthwash, including humectants and flavoring agents (col. 4, lines 11-30). Ryan discloses glycerin and sorbitol and other edible polyhydric alcohols but does not explicitly list propylene glycol as a humectant. Hall's composition is alleged to disclose that his solvent system acts as a carder for the flavoring oils because his solvent system solubilizes the flavoring oils and aids in dispersion of the flavorings oils. The Examiner alleges that it would have been obvious to a person skilled in the art to include propylene glycol of Hall in the teachings of Ryan because Ryan teaches that polyhydric alcohols and flavoring agents can be included in his mouthwash and Hall teaches that propylene glycol helps solubilize and disperse the flavoring oil.

Applicants respectfully disagree with the Examiner's basis for combining the disclosures of these patents because claim 1 recites that the solution does not contain one or more flavoring oils. Claims 31 utilizes the language "consisting essentially of" and as argued in the previous response, this composition cannot contain any component that would materially affect the basic and novel properties of the claimed invention (see page 5 of the previous response). The Examiner has accepted these arguments in regard to the essential nature of the flavoring oil in the Hall solution, and therefore, claim 31 cannot be obvious because the motivation to combine Ryan and Hall is based on the presence of flavoring oil, which cannot be present in claim 31. If there are no flavoring oils in the claimed solution, then there is no motivation to combine Ryan and Hall as the Examiner's rationale for adding the propylene glycol is to solubilize and disperse the flavoring oil.

In regard to claim 34, this claim also contains the phrase "consisting essentially of." Therefore, the arguments regarding claim 31 above, also apply to claim 34. Claims 44 –46 are canceled.

The Examiner admits that Ryan does not disclose a concentration of a cationic antimicrobial agent of about 40% as claimed in claims 14-16, 20, 24, 32 and 45 but states that in the absence of a showing of criticality of this concentration, i.e., 40%, varying the antimicrobial concentration in these claims is considered to be obvious. Applicants respectfully disagree with the Examiner basis for this rejection. As argued above, Ryan does not disclose a solution containing an antimicrobial compound that remotely approaches

the "about 40%" concentration level. Applicants contend that there is no motivation to increase the antimicrobial agent from 0.5% to 40% by mere parameter manipulation. Also as noted above, the many advantages of the claimed concentrated QAC solution on page 6 of the previous response filed on April 30, 2001, as well as the many advantages of the claimed concentrated composition in the paragraph bridging pages 12 and 13 of the specification, should be considered as advantages of the claimed solution and should be taken into consideration by the Examiner in the examination of new claims 47-51.

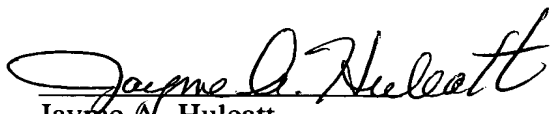
In view of all of these arguments, it is requested that this rejection be withdrawn to all of the rejected claims.

CONCLUSION

The present response is intended to be a complete response to the Examiner's Office Action. It is believed that the above arguments and amendments to the claims place the application in condition for allowance, and a notice to that effect is respectfully requested. If there are any minor issues which can be taken care by telephone, it is requested that the Examiner contact the undersigned attorney at telephone number below.

Respectfully submitted,

November 19, 2001
Date



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MARKED-UP VERSION OF CLAIMS

1. (Amended) A concentrated quaternary ammonium compound solution comprising:

a quaternary ammonium compound with a concentration from greater than 10% by weight; and

at least one solubility enhancing agent,

wherein said solution does not comprise one or more flavoring oils.

34. (Amended) A quaternary ammonium compound solution consisting essentially of:

a quaternary ammonium compound with a concentration of up to about 1% by weight;

at least one solubility enhancing agent**, wherein at least one of said solubility enhancing agents is propylene glycol**; and

water.

37. (Amended) The solution of claim [36] **34**, wherein said solubility enhancing agent [is] **further comprises an agent** selected from the group consisting of a monohydryic alcohol, a dihydric alcohol, a trihydric alcohol, a polyethylene glycol, and a combination thereof